REMARKS

First, in addition to thanking Examiner Kishore for the interview, applicants wish to express their appreciation for the apparent withdrawal of finality of the previous Office action. Applicants understand that this is because certain claims, claims 87-93 were not considered in that action; the present action takes account of them.

The claims have been amended for clarity only. Claim 71, the only independent claim, has been amended to specify that the drug is contained in the lipid/surfactant layer and not carried or deposited in the interior of the nanoparticle. The Examiner has pointed out, on page 4 of the Official action, that the claims "do not exclude the presence of the active agent in the interior." Applicants have based their arguments on the concept that this is the intent of the claims, and this has now been made explicit. Because this has been the basis for applicants' arguments, it is believed no new issues are raised, and that entry of the amendment, though made after final, is proper. Substantially *in haec verba* support for this portion of the amendment to claim 71 is found on page 7 of the specification at lines 16-18. Claim 71 has also been amended to specify that the targeting ligand effects prolonged contact between the lipid bilayer of the cells of a tissue or organ that is targeted with the lipid/surfactant layer of the coated particles. Substantially *in haec verba* support for this portion of the amendment is found on page 6, lines 12-15. The remaining amendment to claim 71 coordinates the effect of the method with the preamble and does not add new matter.

The proposed amendment to claim 87 is intended to place this claim in better position for allowance or appeal. Classes of drugs on the list set forth in claim 87 have simply been deleted, and nothing has been added. Similarly, doxorubicin has been deleted from the list of drugs in claim 89

and antiallergic agents has been deleted from the list of drugs in claim 91 as inconsistent in scope with individual drugs listed previously in that claim.

Clearly no new matter has been added and entry of the amendment is respectfully requested, applicants sincerely believe that the amendments place the claims in a position for allowance and request that the Examiner exercise his discretion to enter them.

There are two outstanding grounds for rejection: claims 71-79 and 82-86 are rejected as assertedly anticipated by any one of three substantially equivalent Lanza patents; all claims (claims 71-79 and 82-93) were rejected as assertedly obvious over any of the Lanza patents alone or in combination with Adler-Moore (U.S. 5,656,287).

Before addressing these rejections directly, applicants point out that the present invention resides in the discovery, clearly not appreciated or described by the disclosure in the primary documents, that having the biologically active agent or drug reside in the surfactant/lipid layer of the nanoparticles and targeting the nanoparticles to the desired tissue or organ permits prolonged contact between the lipid/surfactant layer and the lipid bilayer of the cells contained in the tissue or organ such that their intermingling permits and facilitates delivery of the drug. Nothing of this effect is noted in any of the Lanza patents. Nothing is said in any of the Lanza patents with respect to the location of the drug in the lipid/surfactant layer. Thus, the only manner in which Lanza can anticipate the present invention is under the circumstance that this would be inherent. Applicants will demonstrate below that when the legal criteria for inherency are applied to the facts of the present case, no inherency should be found. This is because inherency requires that the invention claimed be an inevitable result of the disclosure in the prior art. Applicants demonstrate below that neither the exclusive residence of the therapeutic agent in the lipid/surfactant layer coating the

particles nor the prolonged contact between the lipid/surfactant layer and the cellular membrane are inevitable results of practicing the teachings set forth in Lanza.

The proposed amendments to the claims clarify that the drug is contained in the lipid/surfactant layer "and not carried or deposited in the interior of said nanoparticles" and that such prolonged contact is achieved. These requirements are completely supported by the specification as set forth above.

Anticipation

In rejecting claims 71-79 and 82-86 as assertedly anticipated by three Lanza patents, all members of the same family, that are of record, the Office points out that similar compositions to those contained in the claims were used and that the disclosure in each case indicates that the compositions may contain biologically active agents, naming certain specific drugs. The Office states that "it is known in the art that lipophilic agents get incorporated in the lipid bilayer of the liposomes and the hydrophilic agents in the interior." The Office acknowledges the argument in the previous response that the present compositions are not liposomes so that there is no aqueous interior or bilayer; rather both the interior of the particles and the lipid/surfactant outer layer are hydrophobic, but maintains the rejection based on this analogy. It is not clear how this is reasonable, since there is an admission of record that the analogy is flawed.*

* The Office has asserted that inherency exists, because in the case of liposomes which have lipid bilayers surrounding an aqueous interior, hydrophobic drugs would find themselves in the lipid bilayers. Therefore, the Office concludes that the description of Lanza inherently requires the presence of hydrophobic drugs, at least, in the lipid/surfactant layer as required by the claims. Applicants have pointed out that the analogy does not hold because the nanoparticles are hydrophobic throughout. For this reason, the inherency asserted by the Office is not supported by the rationale provided.

The finding of inherent anticipation should be reviewed in light of the case precedent for what is required to find inherency. The standard is quite high, as applicants are certain the Office is aware. Over and over, the Federal Circuit has cited the principle set forth in *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F2d 1264, 20 USPQ2d 1746 (Fed. Cir. 1991) which was actually quoted from two earlier CCPA cases – *In re Oelrich*, 666 F2d 578, 212 USPQ 323, (CCPA 1981) which in turn quoted *Hansgirg v. Kemmer,* 40 USPQ 665 (CCPA 1939).

> Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.

It must be evident that this standard is one that has been followed by the Appeals Court in patent cases for more than half a century.

How, then, is this standard to be interpreted in light of facts in individual cases? Closest in fact pattern to the present case is the holding in *Glaxo, Inc. v. Novopharm, Ltd.*, 52 F3d 1043, 34 USPQ2d 1565 (Fed. Cir. 1995). This case concerned Zantac®. An initial patent on this molecule described the preparation of what came to be known as Form 1. Glaxo later found that a different polymorphic form, designated Form 2, had superior properties. A later patent was filed and issued on Form 2. In an infringement suit against Novopharm, triggered by Novopharm's Abbreviated

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Applicants do not understand at least part of the reason given for finding their arguments not persuasive – "since whether the lipid layer is a bilayer or single layer, the property of the lipophilic compounds is to sequester into the lipid." Applicants did not argue any significance to the lipid layer being a single layer as opposed to a bilayer. The Office asserts that the presence of the lipophilic agent in both the hydrophobic interior and the lipid layer is implicit in Lanza and that the instant claims do not exclude the presence of the active agent in the interior. Applicants do understand this aspect of the Office's position, and the claims have been proposed to be amended to obviate this basis for rejection by simply clarifying claim 71. Again, respectfully, applicants have maintained this is the meaning of the claim all along, so no new issue is now raised.

New Drug Application (ANDA), paragraph 4 certification, Novopharm asserted that one of the examples in Glaxo's earlier patent resulted in Form 2, and although this was not recognized, there was inherent anticipation. In evaluating the proceedings below, the Federal Circuit noted that Novopharm's expert "performed the process disclosed in Example 32 of the '658 (first) patent thirteen times and each time they made Form 2 crystals, not Form 1 as Glaxo claims."

This, however, was *not* good enough to justify a holding of inherent anticipation:

> But the District Court found that the practice of Example 32 could yield crystals of *either* polymorph. It specifically found that Glaxo's David Cullen originally made Form 1 by practicing Example 32 and that Glaxo's expert, Nicholas Crouch, did so as well.

Based on this evidence, the District Court held that anticipation did not exist, and the Federal Circuit affirmed. Thus, the finding of *lack* of inherency was justified even if there was evidence that sometimes, *but not always*, Form 2 was obtained by following the directions in the earlier patent. The legal principle behind this affirmation was explicitly stated to be that quoted above from *Continental Can*. It must be apparent that the requirements of the claimed invention must be met by the teachings of the prior art every single time that they are practiced.

Comparing *Glaxo* to the situation here, it appears that the possibilities are even more open. It is a requirement of the claims that the drug reside in the lipid/surfactant layer, and not in the interior of the particle or anywhere else associated with the particle, and that there be prolonged contact between the lipid/surfactant layer and the cell membrane. It will not be the case that every time the teachings of Lanza are practiced the therapeutic agent resides exclusively in the lipid/surfactant layer and every time Lanza is practiced there will be prolonged contact between the lipid/surfactant layer and the cellular membrane. The manner in which Lanza can be practiced is entirely unspecified, thus permitting a multiplicity of results that do not include those required by

the claims. There are no directions in Lanza for preparing the emulsions of coated perfluorocarbon nanoparticles so as to include a therapeutic agent. The single paragraph that describes this simply says, "[t]he ligand-based binding systems of the invention may also be applied to provide a chemotherapeutic agent or gene therapy system combined with ultrasonic imaging." No other instructions as to how the therapeutic agent or gene therapy delivery system is to be included are found. It would clearly not be suggested to the ordinary practitioner to include the drug in the lipid/surfactant layer as directed in the present application and as illustrated by the examples therein, or to provide for the requisite prolonged contact.

The practitioner, lacking the guidance of the present invention and therefore not understanding that residence in the lipid layer and prolonged contact with the lipid cellular membrane would enhance drug delivery, would have no incentive to use the particular method taught in the present application to include the drug in the emulsion. Many other methods are available and would just as probably be used.

For example, the most straightforward way to include a hydrophilic drug would be to attach it to a lipid anchor that would reside in the lipid/surfactant layer, and permit the drug to reside in the aqueous medium outside the particle. This would not result in the drug being included in the lipid layer as required by the claims – indeed, a spacer might very well be included to distance the drug even farther from the outer surface of the layer. Second, the drug could be suspended in the perfluorocarbon core, including crystalline forms of the drug that could be intimately mixed therewith prior to the preparation of the nanoparticles. This would result in the majority of the drug being included in the core rather than in the lipid layer. Again, unless the practitioner were aware of the present invention, there would be no incentive to ensure that it was included in the outer layer.

Still another approach that would occur to the practitioner is to attach a drug using the same biotin/avidin linking system described in Lanza. Thus, the drug might be coupled to avidin and secured to the particles through biotin-related components of the layer. Again, the drug would not reside in the lipid layer, but in the medium outside of it.

Further, there are no limitations in Lanza on any linker that couples the targeting ligand to the particles. Indeed, a biotin/avidin/biotin bridge as described in Lanza could distance the particles sufficiently from the targeted tissue so that the lipid/surfactant layer would fail to contact the cellular membrane.

Thus, depending on how a practitioner actually constructed the emulsions to include the therapeutic agent (and indeed, the targeting ligand), the therapeutic agent might or might not reside in the lipid/surfactant layer, and might or might not result in prolonged contact. Since no instructions are provided in Lanza, any method of construction, including those set forth above which clearly do not have the required result, can be used. Thus, the disclosure of Lanza falls far short of the standard enunciated in *Continental Can* and applied in an entirely analogous way in *Glaxo*.

For these reasons, it is believed that the invention as now proposed to be claimed in claims 71-79 and 82-86 is not anticipated.

Obviousness

All claims of the application were rejected as assertedly obvious over any of the Lanza patents either alone or in combination with Adler-Moore.

Adler-Moore concerns liposomes, which are not the subject of the present invention. The process of preparation of liposomes may be similar to that in the present application, but it is not

similar enough – the resultant composition is entirely different, as the present application concerns nanoparticles with hydrophobic cores and Adler-Moore concerns liposomes. The method of Lanza does not, as asserted by the Office, involve addition of an aqueous medium to the lipid mixture except in the presence of the perfluorooctylbromide which effects coating of the perfluorooctylbromide with the lipid/surfactant and formation of an emulsion. No liposomes are formed, as applicants are certain the Office would acknowledge. Thus, Adler-Moore appears completely irrelevant.

As to obviousness with regard to the Lanza documents alone, there has been no showing that Lanza suggests delivering drugs by encapsulating them in the outer layer of hydrophobic nanoparticles which are targeted to desired tissues or organs as required by the claims. There is no suggestion in Lanza that targeting hydrophobic particles which contain drugs substantially exclusively in the lipid/surfactant coating and permitting prolonged contact with the bilayers in the cells at the surface of the target tissues or organs would be an effective method to facilitate drug delivery. Thus, if inherent anticipation cannot be shown, none of the Lanza documents defeats patentability of the present claims. The basis for rejection argued here does not encompass anticipation.

As noted above, applicants believe that the Office has failed to show that any claim is inherently anticipated by any Lanza document. However, there are clearly some claims that cannot possibly be considered inherently anticipated. These include claims 87-93; indeed, the Office has never asserted that these claims are anticipated.

Thus, claims 87-93 are clearly free of the cited art, regardless of the fate of claims 71-79 and 82-86 with respect to the rejection for anticipation.

Conclusion

Claim 71 has been proposed to be amended to clarify that the drug to be delivered resides in the lipid/surfactant layer and not in the interior of the nanoparticles. This limitation is completely supported by the specification as noted. The residence of the drug in the lipid/surfactant layer, and the prolonged contact required and achieved by targeting the particles to the desired tissue or organ results in facilitating drug delivery. None of this is suggested by any of the documents cited by the Office. The proposed amendment to claim 71 clearly distinguishes all claims from Lanza.

Applicants have set forth the relevant case law for inherent anticipation and demonstrated that Lanza does not teach a method to construct the particles which would inevitably result in a drug residing in the lipid/surfactant layer or that prolonged contact would be maintained, as would be required for inherent anticipation of the invention as claimed.

There is no assertion that claims 87-93 are anticipated by Lanza and so clearly these claims are free of the art, regardless of what the view of the Office might be regarding claims 71-79 and 82-86. Therefore, applicants believe all claims are in a position for allowance and respectfully request that claims 71-79 and 82-93 be passed to issue.

Again, applicants express their appreciation to Examiner Kishore for his consideration of the arguments advanced at the interview. If further discussion by telephone would be helpful, a call to the undersigned would be much appreciated.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the

cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 532512000401.

Respectfully submitted,

Dated: November 29, 2005 By: Kate H. Murashige

Kate H. Murashige
Registration No. 29,959
MORRISON & FOERSTER LLP
12531 High Bluff Drive
Suite 100
San Diego, California 92130-2040
Telephone: (858) 720-5112
Facsimile: (858) 720-5125

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U.S. Court of Appeals
Federal Circuit

Glaxo Inc. v. Novopharm Ltd.

No. 94-1026

Decided April 21, 1995

PATENTS

1. Patentability/Validity — Anticipation — Prior art (§115.0703)

Federal district court properly rejected defendant's contention that patent for crystalline ranitidine hydrochloride was anticipated by process disclosed in prior patent, since court's conclusion that practice of process did not always produce compound of patent in suit, and that compound was therefore not inherent in prior art process, is not clearly erroneous.

2. Infringement — Defenses — Fraud or unclean hands (§120.1111)

Federal district court did not err by rejecting inequitable conduct defense, even though court found that declaration submitted to overcome initial rejection of application for claims in suit included material misrepresentation, since court's conclusion that defendant failed to prove intent to deceive by clear and convincing evidence is not wrong as matter of law.

3. Patentability/Validity — Specification — Best mode (§115.1107)

Specification's failure to disclose "azeotroping" process for producing claimed crystalline ranitidine hydrochloride does not render patent invalid for failure to disclose best mode for producing compound, since there is no evidence that inventor knew of azeotroping process or concealed it at time application was filed; knowledge of azeotroping process held by inventor's employers cannot be imputed to inventor for purposes of finding best mode violation, since 35 USC 112, first paragraph, clearly states that best mode to be disclosed is that "contemplated by the inventor," and since best mode inquiry, in accordance with statutory language and case law, must therefore be grounded in knowledge of inventor alone.

Particular patents — Chemical — Ranitidine hydrochloride

4,521,431, Crookes, aminoalkyl furan derivative, judgment that patent is not invalid and has been infringed is affirmed.

Appeal from the U.S. District Court for the Eastern District of North Carolina, Boyle, J.; 29 USPQ2d 1126.

Action by Glaxo Inc. and Glaxo Group Ltd. against Novopharm Ltd., for patent infringement. From judgment for plaintiffs, defendant appeals. Affirmed; Mayer, J., dissenting.

Stephen B. Judlowe, William G. Todd, and Janet B. Linn, of Hopgood, Calimafde, Kalil, Blaustein & Judlowe, New York, N.Y.; Steven P. Lockman, of Arnold & Porter, Washington, D.C.; Joseph W. Eason, of Moore & Van Allen, Raleigh, N.C., for Glaxo Inc. and Glaxo Group Ltd.

Robert F. Green, John E. Rosenquist and Jeffrey S. Ward, of Leydig, Voit & Mayer, Chicago, Ill., for Novopharm Ltd.

Before Archer, chief judge, and Rich and Mayer, circuit judges.

Rich, J.

Novopharm Ltd. (Novopharm) appeals the judgment of the United States District Court for the Eastern District of North Carolina, *Glaxo, Inc. v. Novopharm Ltd.*, 830 F. Supp. 871, 29 USPQ2d 1126 (E.D.N.C. 1993), that United States Patent No. 4,521,431 was not invalid and was infringed, and enjoining Novopharm from the commercial manufacture or sale of the patented crystalline form of ranitidine hydrochloride. We affirm.

Background

Glaxo Inc. and Glaxo Group Ltd. (collectively Glaxo) are the owner and exclusive United States licensee, respectively, of United States Patent No. 4,521,431 ('431 patent). The '431 patent claims a specific crystalline form of the compound ranitidine hydrochloride, designated as "Form 2," which Glaxo markets as an antiulcer medication under the brand name Zantac.[1] The '431 patent issued on June 4, 1985.

[1] Claims 1 and 2 of the '431 patent, in issue here, read:

1. Form 2 ranitidine hydrochloride characterised by an infra-red spectrum as a mull in mineral oil showing the following main peaks: [list of peaks]

2. Form 2 ranitidine hydrochloride according to claim 1 further characterised by the following x-ray powder diffraction pattern expressed in terms of "d" spacings and relative intensities (1) (s=strong, m=medium, w=weak, v=very, d=diffuse) and obtained by the Debye Scherrer method in a 114.6 mm diameter camera by exposure for 12 hours to CoK_a radiation and for 3 hours to CuK_a radiation: [table]

In 1976, Glaxo chemists investigating potential antiulcer medications synthesized an aminoalkyl furan derivative, later named ranitidine, which proved to be a potent histamine blocker, inhibiting the secretion of stomach acid. Later that year, Glaxo filed an application for a patent on ranitidine in the United Kingdom. It followed with an application for a United States patent, which issued as No. 4,128,658 ('658 patent) on December 5, 1978. The '658 patent claims a number of structurally similar compounds, including ranitidine and its hydrochloride salt. It discloses one method for preparing ranitidine hydrochloride, set forth in the '658 patent as Example 32.[2]

Glaxo prepared large quantities of ranitidine hydrochloride between 1977 and 1980 for use in toxicology and clinical studies. Instead of using the process of Example 32, however, Glaxo's chemists prepared this material using a similar process that they labeled Process 3A. They later developed a more efficient method that they called Process 3B. Until April 15, 1980, both Process 3A and Process 3B yielded ranitidine hydrochloride identical in all respects to that originally produced using the Example 32 procedure.

On that date, however, Glaxo's Derek Crookes used Process 3B to prepare crystalline ranitidine hydrochloride that was visibly different from all previous batches of the salt. The difference was confirmed by infrared (IR) spectroscopy and x-ray powder diffraction, which revealed that the new product was a crystalline form, or polymorph, of ranitidine hydrochloride that differed from the previously known form. Glaxo began to refer to this new polymorph as Form 2 ranitidine hydrochloride (designating the old polymorph as Form 1).

Because Form 2 had better filtration and drying properties, making it better suited for commercial applications, Glaxo decided to proceed with commercialization of Form 2 rather than Form 1. Form 2 was hampered by poor flow properties, however, which made the material difficult to measure and dispense in its pure form. Accordingly, Glaxo scientists developed a novel azeotroping process[3] to granulate the Form 2 salt, which made it much easier to make into pharmaceutical compositions. This process was the subject of a British patent application that Glaxo eventually abandoned without disclosing the process to the public.

Glaxo filed a patent application covering Form 2 ranitidine hydrochloride in the United Kingdom on October 1, 1980. It filed a United States application thereon the next year, which eventually issued as the '431 patent in suit. When George Graham Brereton, Glaxo's patent officer initially charged with pursuing the United States application, learned of the azeotropic granulation process and Glaxo's desire to keep that process secret, he recommended that Glaxo not claim pharmaceutical compositions of the Form 2 salt for fear of violating the best mode requirement. Brereton apparently believed that disclosure of the azeotroping process would be necessary because it was the best way to make the Form 2 salt for use in preparing pharmaceutical compositions. He later moved to another position at Glaxo. The U.S. application was eventually amended to include pharmaceutical composition claims, but Glaxo did not amend the specification to disclose the azeotroping process.

On August 9, 1991, Novopharm Ltd. filed an Abbreviated New Drug Application (ANDA) with the Food and Drug Administration (FDA), seeking FDA approval to manufacture and sell a generic version of Form 2 ranitidine hydrochloride beginning December 5, 1995, the expiration date of the '658 patent, well before the expiration date of the '431 patent in 2002. Glaxo filed this suit for patent infringement on November 13, 1991, alleging technical infringement of claims 1 and 2 of the '431 patent by the ANDA filing as provided in 35 U.S.C. § 271 (e)(2) (1988). Novopharm admitted in-

The '431 patent also claims various pharmaceutical compositions and methods of using Form 2 ranitidine hydrochloride. These claims are not at issue in this case.

[2] Developed by Glaxo's David Collin in June 1977, that method involves dissolving ranitidine in industrial methylated spirit containing dissolved hydrogen chloride gas. Ethyl acetate is added to the solution, and ranitidine hydrochloride precipitates from solution as a crystalline solid characterized by a melting point of 133-134°C.

[3] Azeotroping is a technique for separating a chemical mixture, the components of which would otherwise be difficult to separate because of the similarity of their boiling points. An additional substance is added to the mixture, selected for its ability to interact with a component of the original mixture to form an azeotrope — a mixture of substances "the composition of which does not change upon distillation." *See McGraw-Hill Dictionary of Scientific and Technical Terms* 162 (4th ed. 1989). If the proper substance is selected, the resulting azeotrope will have a boiling point that differs substantially from the desired component of the original mixture. The desired component can then be successfully separated from the azeotrope by distillation. *See Hawley's Condensed Chemical Dictionary* 109 (11th ed. 1987).

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fringement of the claims, but contended that the '431 patent was invalid because it was anticipated by the disclosure of the '658 patent.

Novopharm later amended its answer to add the defense of inequitable conduct arising from alleged false and misleading affidavits provided to the U.S. Patent and Trademark Office (PTO) during prosecution of the applications from which the '431 patent issued. Finally, on June 21, 1993, Novopharm sought summary judgment based on a third defense, Glaxo's alleged failure to disclose the best mode of practicing the claimed invention. The trial court denied the motion, and the case was tried to the court beginning on August 9, 1993.

On the question of anticipation, the court found that Novopharm had not carried its burden of proving by clear and convincing evidence that practice of Example 32 of the '658 patent always produced Form 2 ranitidine hydrochloride, so that Form 2 was not inherently disclosed by Example 32. As for inequitable conduct, the court agreed with Novopharm that the affidavits presented to the examiner were misleading and material, but it found that Novopharm had failed to prove any deceptive intent. The court also concluded that there was no violation of the best mode requirement because Novopharm had not proved that Crookes, the inventor, knew of the best mode, the statute and this court's precedent providing that knowledge by the inventor himself is required. Accordingly, the court held that the '431 patent was not invalid, was enforceable and infringed, and ordered that Novopharm refrain from commercial manufacture or sale of Form 2 ranitidine hydrochloride before the '431 patent expires. Novopharm appeals.

Discussion

I. *Example 32, anticipation*

We consider first Novopharm's argument that the district court erred in holding that Novopharm did not prove that the claims in suit of the '431 patent were anticipated by Example 32 of the '658 patent. Anticipation is a factual matter, which we review under the clearly erroneous standard. *Diversitech Corp. v. Century Steps Inc.*, 850 F.2d 675, 677, 7 USPQ2d 1315, 1317 (Fed. Cir. 1988). A claim is anticipated and therefore invalid only when a single prior art reference discloses each and every limitation of the claim. 35 U.S.C. § 102(a) (1988); *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 1571, 230 USPQ 81, 84 (Fed. Cir. 1986). The disclosure need not be express, but may anticipate by inherency where it would be appreciated by one of ordinary skill in the art. *Continental Can Co. USA Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

[1] Novopharm maintains that the invention claimed in the '431 patent, ranitidine hydrochloride in its Form 2 crystalline polymorph, is inherently disclosed in the '658 patent because the practice of Example 32 always yields ranitidine hydrochloride in its Form 2 polymorph. Novopharm's experts performed the process disclosed in Example 32 of the '658 patent thirteen times and each time they made Form 2 crystals, not Form 1 as Glaxo claims.

But the district court found that the practice of Example 32 could yield crystals of either polymorph. It specifically found that Glaxo's David Collin originally made Form 1 by practicing Example 32, and that Glaxo's expert, Nicholas Crouch, did too.[4] We are not persuaded that these findings are clearly erroneous. The district court correctly rejected the anticipation defense.

II. *Inequitable Conduct*

Novopharm contends that the trial court erred as a matter of law in declining to infer an intent to deceive from Glaxo's material misrepresentations to the PTO. The charge of inequitable conduct arises from a declaration submitted by John Harold Hunt, the head of Glaxo's spectroscopy group, in response to a rejection in light of the product of Example 32 of the '658 patent.[5]

To prevail on its inequitable conduct defense, Novopharm had to show by clear and convincing evidence that Glaxo misrepresented facts to the PTO during prosecution of the '431 patent, that the misrepresentation was material, and that Glaxo acted with the intent to deceive the PTO. *Kingsdown Medical Consultants Ltd. v. Hollister Inc.*, 863 F.2d 867, 872, 9 USPQ2d 1384, 1389 (Fed. Cir. 1988). We review the district court's ultimate determination for abuse of discretion; the subsidiary factual questions of whether there was a misrepresentation, its materiality, and intent to deceive are reviewed for clear error. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1215,

[4] Novopharm suggests that the court was wrong in finding that these experiments were within the scope of Example 32 because they employed procedures that sometimes departed from the strict letter of Example 32. The district court found that one skilled in the art would understand that these procedures were consistent with the teaching of Example 32. We do not see where the court erred in this finding.

[5] The case was complicated by the trial court's inability to hear testimony from Hunt due to his death in 1985.

18 USPQ2d 1016, 1028 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991).

On August 28, 1983, the examiner rejected claims 1 and 2 of Glaxo's Form 2 ranitidine hydrochloride patent application as anticipated by or obvious in light of the disclosure of the '658 patent. Glaxo argued that its claims were drawn to a specific crystalline form of ranitidine hydrochloride different from the compound disclosed in the '658 patent. The examiner asked for a showing that the claimed Form 2 ranitidine hydrochloride was patentably distinct from the prior art composition.

To overcome the rejection, Glaxo submitted Hunt's declaration comparing the IR spectra and x-ray powder diffraction patterns of the two crystalline forms. The declaration concluded that there were significant differences between the two products; a second declaration attested to the practical differences between the two polymorphs that made the Form 2 ranitidine hydrochloride preferable for commercialization.

Intent is often inferred from surrounding circumstances when a material misrepresentation is shown. *Paragon Podiatry Lab. v. KLM Lab.*, 984 F.2d 1182, 1189, 25 USPQ2d 1561, 1567 (Fed. Cir. 1993). But an inference is not required in every case, even when the misrepresentation is in affidavit form. Glaxo admits that the Form 1 data submitted with the Hunt declaration was not obtained from ranitidine hydrochloride prepared according to Example 32 of the '658 patent. The trial court concluded from this that the declaration was misleading, because it suggested falsely that the data had been obtained from the product of Example 32. The court also found that the misstatement was material. But it nevertheless concluded that an inference of fraudulent intent was unwarranted. We have not been persuaded otherwise.

[2] The court found that as head of spectroscopy, Hunt was familiar with data obtained from Form 1 material, including that originally made by Collin according to Example 32. He knew that in each case the Form 1 data was different from that obtained for Form 2. The court found that there was no difference between the IR spectrum of the Form 1 hydrochloride obtained according to Example 32 and that obtained by other methods. Likewise, although the Example 32 material was never subjected to x-ray diffraction analysis, material produced by other methods yielded a consistent powder diffraction pattern that was different from that obtained from Form 2 crystals; this material exhibited an IR spectrum identical to that of the Example 32 material.

The trial court concluded that Hunt did not believe there were any differences between material produced using Example 32 and the material from which he obtained the data analyzed in his declaration. Accordingly, the court found that Novopharm failed to carry its burden of proving intent to deceive by clear and convincing evidence. Although this conclusion is debatable, that is not sufficient reason to reverse in the absence of firm and definite belief that the district court erred.

III. *Best Mode*

Novopharm next asserts that Glaxo failed to disclose the best mode of practicing the invention, that is, the azeotroping process it uses to formulate the claimed Form 2 ranitidine hydrochloride into pharmaceutical compositions. The best mode defense arose little more than two months before trial just after Glaxo produced documents based on which Novopharm filed a motion for summary judgment of invalidity for failure to disclose the best mode. Less than a week before trial, the district court denied Novopharm's motion stating that "the court cannot hold as a matter of law that Dr. Crookes knew that the azeotroping process was the best mode of manufacturing ranitidine hydrochloride, and summary judgment must therefore be denied." *Glaxo, Inc. v. Novopharm Ltd.*, 830 F.Supp. 869, 871 (E.D.N.C. 1993). The district court further stated that it reserved for trial "ruling on the question of whether and to what extent the knowledge of other Glaxo employees and agents may be imputed to Dr. Crookes for purposes of finding a best mode analysis [sic, violation]." *Id.*

At trial, Novopharm produced evidence that officials at Glaxo knew of the azeotroping process and considered it to be the best mode of making Form 2 ranitidine hydrochloride into a pharmaceutical composition. Novopharm argued in district court, as it does here, that the knowledge of the azeotroping process by Glaxo officials should be imputed to inventor Crookes for purposes of finding a best mode violation.

The trial court found Novopharm's argument to have some "intuitive appeal" since Glaxo "has enjoyed the monopoly the issued patent provides." *Glaxo*, 830 F.Supp. 871, 881-82, 29 USPQ2d 1126, 1134 (E.D.N.C. 1993). Indeed, the trial court stated that if it were to impute the knowledge of others to the inventor of the '431 patent, "then clearly the court would be required to find a best mode violation." *Id.* at 882. The trial court concluded, however, that the statute, 35 U.S.C. § 112, first paragraph, and this court's holding in *Texas Instruments, Inc. v.*

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United States International Trade Commission, 871 F.2d 1054, 10 USPQ2d 1257 (Fed. Cir. 1989) do not permit using imputed knowledge in a best mode analysis. The district court concluded that Novopharm "as a matter of law . . . failed to show the '431 patent should be invalidated based on a best mode violation." *Id.* at 882. On appeal, Novopharm asserts that the district court erred as a matter of law in holding that a best mode defense cannot be found in the absence of proof that the inventor knew of that mode.

The statutory provision at issue sets forth that:

> The specification . . . shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112, first paragraph (1988).

[3] The statutory language could not be clearer. The best mode of carrying out an invention, indeed if there is one, to be disclosed is that "contemplated by the inventor." That the best mode "belongs" to the inventor finds consistent support in previous statutory language as well.[6] Additionally, the commentary on the 1952 Patent Act states with respect to the best mode provision that "[t]his requirement, it should be noted, is not absolute, since it only requires disclosure of the best mode contemplated by the inventor, presumably at the time of filing the application." P.J. Federico, Commentary on the New Patent Act, 35 U.S.C.A. 1, 25 (1954).

In arguing that Glaxo did not comply with the best mode requirement of § 112, first paragraph, Novopharm relies on *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991), for the proposition that the best mode requirement lies at the heart of the statutory quid pro quo of the patent system. This is true enough. However, *Amgen*, consistent with the statute, speaks of the best mode requirement in terms of the best mode contemplated by the inventor. *Amgen*, 927 F.2d at 1210, 18 USPQ2d at 1024 ("Our case law has interpreted the best mode requirement to mean that there must be no concealment of a mode known *by the inventor* to be better than that which is disclosed.") (emphasis added). In fact, as we have previously stated, the sole purpose of the best mode requirement "is to restrain *inventors* from applying for patents while at the same time concealing from the public preferred embodiments of *their inventions* which *they* have in fact conceived." *Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 926, 16 USPQ2d 1033, 1035 (Fed. Cir. 1990) (emphasis added) (*quoting In re Gay*, 309 F.2d 769, 772, 135 USPQ 311, 315 (CCPA 1962)); *see Dana Corp. v. IPC Ltd. Partnership*, 860 F.2d 415, 419, 8 USPQ2d 1692, 1696 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1067 (1989)

The best mode inquiry focuses on the inventor's state of mind at the time he filed his application, raising a subjective factual question. *Chemcast*, 913 F.2d at 926, 16 USPQ2d at 1035. The specificity of disclosure required to comply with the best mode requirement must be determined by the knowledge of facts within the possession of the inventor at the time of filing the application. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1535, 3 USPQ2d 1737, 1745 (Fed. Cir.), *cert. denied*, 484 U.S. 954 (1987).

That the best mode inquiry is grounded in knowledge of the inventor is even more evident upon contrasting the best mode requirement of § 112 with the enablement requirement of that section. *Chemcast*, 913 F.2d at 926, 16 USPQ2d at 1035. "Enablement looks to placing the subject matter of the claims generally in the possession of the public." *Spectra-Physics*, 827 F.2d at 1532, 3 USPQ2d 1742. Best mode looks to whether specific instrumentalities and techniques have been developed by the inventor and known to him at the time of filing as the best way of carrying out the invention. *Id.*; *Chemcast*, 913 F.2d at 927-28, 16 USPQ2d at 1036. The enablement requirement, thus, looks to the objective knowledge of one of ordinary skill in the art, while the best mode inquiry is a subjective, factual one, looking to the state of the mind of the inventor. Indeed, recently this court in addressing whether an applicant's best mode had to be updated upon filing a continuation application affirmed that the best mode requirement "focuses on what the *inventor* knows." *Transco Prods. Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 558, 32 USPQ2d 1077,

[6] The 1793 Act stated: "in the case of any machine [the inventor] shall fully explain the principle, and the several modes in which he has contemplated the application of that principle or character, by which it may be distinguished from other inventions." Act of Feb. 21, 1793, ch. 11, § 3, 1 Stat. 318.

The 1836 Act stated: "in case of any machine, [the inventor] shall fully explain the principle, and the several modes in which he has contemplated the application of the principle or character by which it may be distinguished from other inventions." Act of July 4, 1836, ch. 357, § 6, 5 Stat. 117.

The Act of 1870 changed the 'several modes' provision of the previous Acts to the present-day 'best mode.' Act of July 8, 1870, ch. 230, § 26, 16 Stat. 198.

1083 (Fed. Cir. 1994) (emphasis added), *cert. denied*, 130 L.2d 1069 (1995)

Based on the clear wording of the statute and our case law, the trial court properly rejected Novopharm's "imputed knowledge" best mode defense. As the trial court correctly noted, we held in *Texas Instruments* that there was no violation of the best mode requirement of § 112 by reason of knowledge of the *purported* best mode on the part of T.I. employees, *other than the inventor*, in the manufacturing group when the inventor did not know of or conceal this best mode. *Texas Instruments*, 871 F.2d at 1061, 10 USPQ2d at 1262.

There is simply no evidence in the record before us, indeed Novopharm points to none, that the inventor of the '431 patent knew of and concealed the azeotroping process when his application was filed. Inventor Crookes in a declaration in opposition to Novopharm's best mode summary judgment motion stated "I did not know of any azeotroping of ranitidine hydrochloride, or of its benefits, prior to commencement of this litigation. I did not — indeed, could not — consider the azeotrope process a 'best mode' of making ranitidine hydrochloride tablets at the time of filing any patent application." Crookes indicated that he worked in a different department than those who developed the azeotroping process.

As the district court observed, the record does indicate, however, that others at Glaxo knew of the azeotroping process and knew that this process would be used commercially to produce pharmaceutical forms of the claimed product.[7] The record also indicates that these individuals as well as their English patent agent were concerned that failure to disclose the azeotroping process may present a best mode problem. However, in neither instance did Glaxo nor its patent agent appropriately consider that inventor Crookes knew nothing of the azeotroping process. That Glaxo thought it may have a best mode problem either because of its incorrect or incomplete consideration of U.S. patent law does not make it so.

Novopharm maintains that Glaxo intentionally isolated Crookes from knowledge of the azeotroping process leaving "it to others to commercialize and reduce the invention to practice." Thus, Novopharm fears that Glaxo purposefully prevented the inventor from gaining knowledge of the most advantageous application for his invention, the azeotroping process, so that that process could be maintained as a trade secret. That fear does not equate with a best mode violation.

In this case, Crookes was unconcerned with the commercialization of the claimed compound. It is undisputed that Crookes invented a compound and was not involved in whatever processes were to be used to commercially produce it. Therefore, whether Glaxo deliberately walled off the inventor is irrelevant to the issue of failure of his application to disclose the best mode known to him.

In arguing that Crookes was screened from knowledge, Novopharm relies on testimony of Glaxo's in-house patent agent that Crookes was not consulted "at any time" during the preparation of the application that matured into the '431 patent. This however, completely ignores the requirement that patents are applied for "in the name of the actual inventor or inventors" according to 37 C.F.R. § 1.41(a) (1983). The inventor(s) must submit an oath or declaration attesting that they have "reviewed and understand[ ] the contents of the specification" and believe "the named inventor or inventors to be the original and first inventor or inventors of the subject matter which is claimed and for which a patent is sought." 37 C.F.R. § 1.63(b)(1), (2) (1992); see also 37 C.F.R. § 1.51(a)(2) (1992). Moreover, this court in *Sun Studs, Inc. v. Applied Theory Associates, Inc.*, 772 F.2d 1557, 1568, 227 USPQ 81, 89 (Fed. Cir. 1985), recognized that 35 U.S.C. § 111 (1988) "requires that the *inventor* must apply for the patent." *Sun Studs*, 772 F.2d at 1568, 227 USPQ at 89 (emphasis in original). Novopharm has not alleged that these requirements were violated.

It is therefore presumed that Crookes, the inventor and applicant, must have reviewed the specification and signed the required declaration before the application was filed. Without more, Novopharm is simply wrong when it alleges that Crookes had nothing to do with determining what needed to be disclosed in his patent application.

Novopharm additionally contends that looking solely to the inventor's knowledge in a best mode analysis "makes a mockery of the best mode requirement, and fosters a 'head in the sand' mentality for corporate applicants."

However, the practical reality is that inventors in most every corporate scenario cannot know all of the technology in which their

[7] The claims at issue are not directed to a pharmaceutical compound. Therefore, there may be a question whether the azeotroping process is indeed the best mode of carrying out the *claimed* invention. *See Chemcast*, 913 F.2d at 927, 16 USPQ2d at 1036. In view of our decision, however, it is not necessary for us to reach this issue.

employers are engaged. Therefore, whether intentionally or not, inventors will be effectively isolated from research no matter how relevant it is to the field in which they are working. Separating scenarios in which employers unintentionally isolate inventors from relevant research from instances in which employers deliberately set out to screen inventors from research, and finding a best mode violation in the latter case, would ignore the very words of § 112, first paragraph, and the case law as it has developed, which consistently has analyzed the best mode requirement in terms of knowledge of and concealment by the inventor. Congress was aware of the differences between inventors and assignees, *see* 35 U.S.C. §§ 100(d) and 152, and it specifically limited the best mode required to that contemplated by the inventor. We have no authority to extend the requirement beyond the limits set by Congress.

The dissent argues that imputing knowledge of others than the inventor to the inventor for purposes of considering what was "contemplated by the inventor" in a best mode analysis "may be necessary under appropriate circumstances, to protect the public's 'paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct.'" The dissent contends that such knowledge can be imputed to the inventor under principles of agency law stating that, "[a]n agent's acts and knowledge can be imputed to the principal when necessary to protect the interests of others, so long as the acts or knowledge in question fall within the scope of the agent's authority," citing Restatement (Second) of Agency, § 261.

The Restatement defines agency as "the fiduciary relation which results from the manifestation of consent by one person to another that the other shall act on his behalf and subject to his control, and consent, by the other so to act." Restatement (Second) of Agency, § 1.

The flaw in the dissent's analysis is that a patent attorney[8] does not enter into an agency relationship with the inventor for purposes of what is disclosed in the inventor's patent application. Simply, the inventor never authorizes his patent attorney to "act on his behalf" with respect to disclosing the invention. Or, in the terms used by the dissent, the scope of the patent attorney's authority does not include inventing, i.e., either supplementing or supplanting the inventor's knowledge of his own invention. Rather, the information disclosed in the inventor's patent application must be that which is actually known to him. The statute requires that he submit an oath to this effect. *See* 35 U.S.C. § 115 (1988).

An agency relationship may exist during prosecution before the PTO where the patent attorney is acting on the inventor's behalf. *See* 37 C.F.R. 1.56(a) (1992). An agency relationship does not exist, however, with respect to what an inventor must disclose in order to obtain a patent on his invention, which includes, of course, any best mode under § 112. Therefore, in addition to being inconsistent with § 112, as explained above, because an agency relationship does not exist for purposes of what is disclosed in a patent application, it would be improper to impute a patent attorney's knowledge of a best mode to the inventor for purposes of finding a best mode violation.

In any case, the dissent's application of general agency principles to the analysis of best mode disclosure under § 112 is an entirely new idea and is not existing law.

The trial court here correctly noted that this court has "found that the absence of a showing of actual knowledge by the inventor was dispositive of the defendant's best mode argument" and held that the law "does not permit using *imputed knowledge*" in a best mode defense. *Galxo*, 830 F. Supp. at 881-82, 29 USPQ2d at 1135 (emphasis added). The district court therefore correctly rejected the best mode defense.

IV. *Conclusion*

Accordingly, the judgment of the United States District Court for the Eastern District of North Carolina is affirmed.

AFFIRMED

Mayer, J., dissenting.

With this case, the court blesses corporate shell games resulting from organizational gerrymandering and willful ignorance by which one can secure the monopoly of a patent while hiding the best mode of practicing the invention the law expects to be made public in return for its protection. Because I believe this is a perverse interpretation of the law, I dissent.

The best mode requirement arises from the first paragraph of 35 U.S.C. § 112 (1988), which provides that the patent speci-

[8] A "patent agent" is subsumed within this term as a patent agent acts as the inventor's attorney before the PTO. The label "patent agent" does not mean there is an agency relationship, rather than an attorney-client relationship, between the inventor and such individual for all purposes.

fication "shall set forth the best mode contemplated by the inventor of carrying out his invention." The best mode inquiry is twofold: first, did the inventor know of a preferred mode or embodiment of the invention; and second, did the inventor disclose that mode sufficiently to allow those skilled in the art to practice it. *Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 928, 16 USPQ2d 1033, 1036 (Fed. Cir. 1990). The first question is largely subjective, looking to the inventor's knowledge and belief. The second is more objective, focusing on the scope of the invention and the level of skill in the art. *Id.* Compliance with the best mode requirement is a factual question, which we review for clear error. *Engel Indus. Inc. v. Lockformer Co.*, 946 F.2d 1528, 1531, 20 USPQ2d 1300, 1302 (Fed. Cir. 1991). But this assumes a correct understanding of the relevant law, which we review de novo. *See Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1536, 3 USPQ2d 1737, 1745 (Fed. Cir. 1987).

Novopharm says Glaxo did not disclose the best mode of practicing the invention — the azeotropic granulation process it used to formulate ranitidine hydrochloride into pharmaceutical compositions. This defense became relevant only late in the game when, on June 2, 1993, Glaxo produced some documents that indicated that it had withheld information about the granulation process. Novopharm moved for summary judgment based on the best mode violation, which the district court denied, *Glaxo, Inc. v. Novopharm Ltd.*, 830 F.Supp. 869 (E.D.N.C. 1993), but allowed Novopharm to present the best mode defense at trial. Novopharm tried to take discovery on the issue, including a deposition of Crookes, the named inventor of the '431 patent, and Collin, his immediate supervisor. After Glaxo resisted and sought a protective order, the district court denied Novopharm any discovery, and the case proceeded to trial on August 9, 1993. At the close of Novopharm's case-in-chief on its best mode defense, the court decided to rule on that question as a matter of law, no factual issues remaining. Glaxo presented no evidence on the issue. The court held that because Crookes had no personal knowledge of the best mode, there was no requirement that it be disclosed.

Glaxo first suggests that the azeotropic granulation process was not an appropriate candidate for disclosure because it fell outside of the claimed invention. Rather, Glaxo says the process is simply a production technique useful in the formulation of ranitidine hydrochloride into pharmaceutical compositions. It says the process is therefore relevant, if at all, only to the claims of the '431 patent that cover such compositions. No such claims are at issue here, so Glaxo says the best mode should not be considered.

But the statutory language demands that the patent disclose the best mode of "carrying out" the claimed invention. As the district court recognized, this language encompasses not only modes of making the invention, but of using it as well. *See Christianson v. Colt Indus. Operating Corp.*, 822 F.2d 1544, 1563, 3 USPQ2d 1241, 1255 (Fed. Cir. 1987), *vacated on other grounds*, 486 U.S. 800 [7 USPQ2d 1109] (1988). The azeotroping process was the best way to formulate raw ranitidine hydrochloride into pharmaceutical compositions suitable for use as a drug in human patients, the only use Glaxo contemplated for the invention. Glaxo admits the process was not generally known to those skilled in the art. Accordingly, the court could have found that disclosure of the process was required by section 112, so long as the other, subjective, elements of the best mode test were met. *Cf. Chemcast*, 913 F.2d at 930, 16 USPQ2d at 1038 ("Whether characterizable as 'manufacturing data,' 'customer requirements,' or even 'trade secrets,' information necessary to practice the best mode simply must be disclosed.").

The best mode inquiry begins with what the inventor knew when he filed his application. This subjective part of the inquiry traditionally rests on the factual question whether the inventor actually contemplated a preferred mode. *Chemcast*, 913 F.2d at 928, 16 USPQ2d at 1036. But inquiry is not limited to the inventor's actual knowledge.

The court believes *Texas Instruments, Inc. v. United States International Trade Commission*, 871 F.2d 1054, 10 USPQ2d 1257 (Fed. Cir. 1989), expressly limited best mode to the inventor's actual knowledge, but that case includes no such limitation. We merely agreed with the Commission that Texas Instrument's computer component patents were not invalid for failure to disclose the alleged best mode, a so-called "word boost" feature, because " '[t]he record does not disclose that the applicant knew of or concealed a better mode than he disclosed.' " 871 F.2d at 1061, 10 USPQ2d at 1262 (quoting Commission findings).

The problem arises from reading one sentence of the *Texas Instruments* opinion out of context. We said that "[t]he fact that Texas Instruments may have manufactured a DRAM containing a different or better form of boosting means is not pertinent to whether the specification disclosed" the best

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ɜnized, this language encom-
ly modes of making the
of using it as well. *See Colt Indus. Operating Corp.*, 1563, 3 USPQ2d 1241, 1255), *vacated on other grounds*, ' USPQ2d 1109] (1988). The ocess was the best way to ranitidine hydrochloride into l compositions suitable for ı human patients, the only use ılated for the invention. Glaxo cess was not generally known l in the art. Accordingly, the ve found that disclosure of the quired by section 112, so long ıbjective, elements of the best ɜ met. *Cf. Chemcast*, 913 F.2d lSPQ2d at 1038 ("Whether e as 'manufacturing data,' uirements,' or even 'trade se-ıtion necessary to practice the ıply must be disclosed.").
ode inquiry begins with what new when he filed his applica-ective part of the inquiry tradi-ɔn the factual question whether actually contemplated a pre-*Chemcast*, 913 F.2d at 928, 16 036. But inquiry is not limited ɔr's actual knowledge.
believes *Texas Instruments*, *d States International Trade* 871 F.2d 1054, 10 USPQ2d ir. 1989), expressly limited best nventor's actual knowledge, but ɔludes no such limitation. We ed with the Commission that ument's computer component ɜ not invalid for failure to dis-lleged best mode, a so-called " feature, because " '[t]he rec-disclose that the applicant knew ıled a better mode than he dis-1 F.2d at 1061, 10 USPQ2d at ıg Commission findings).
em arises from reading one sen-*Texas Instruments* opinion out We said that "[t]he fact that uments may have manufactured ɔontaining a different or better ɔsting means is not pertinent to ɜ specification disclosed" the best

mode known to the inventors. *Id.* The court reads this to parallel the facts of our case — that the employer of the named inventors developed the alleged best mode wholly without the inventor's knowledge, and that there was no best mode problem because the inventors did not know of it.

But as our opinion in *Texas Instruments* shows, the inventors did know of the word boost feature, but did not believe that it was part of the best mode. *Id.* ("[T]hat the inventors themselves did not consider the 'word boost' feature to be part of the best mode of their invention refutes any argument that the inventor 'knew of and concealed a better mode than he disclosed.' "). Accordingly, *Texas Instruments* stands only for the unremarkable proposition that there is no best mode violation where the inventor knew of the alleged mode and did not consider it to be a part of the preferred embodiment. It says nothing about whether specific knowledge of a best mode by a corporate assignee/employer may be imputed to the inventor/employee. Nor does any other precedent of this court.

As the district court recognized, "Glaxo, and not Crookes individually, . . . both directed the patent prosecution and has enjoyed the monopoly the issued patent provides." 830 F.Supp. at 881-82. Glaxo employees acted as agents for inventor Crookes during prosecution of the U.S. application. They were also agents for Glaxo, the assignee of the application and later the owner of the '431 patent. And that is the crucial point: Glaxo, not Crookes, brought this suit against Novopharm for infringement of the patent. Accordingly, Glaxo's conduct and knowledge during prosecution is important to the resolution of this case; it is not irrelevant, as the court says.

Glaxo says, and the court agrees, that it did not have to disclose the azeotroping process because Crookes did not know of that method of preparing pharmaceutical compositions of Form 2 ranitidine hydrochloride. On the record before us, one wonders how Glaxo could have been sure of what Crookes knew. Brereton, the Glaxo employee charged with initiating the application for the '431 patent, testified that he did not consult Crookes, the named inventor, at any time. Instead, in accordance with Glaxo's standard patent policy, Brereton conferred with Crookes' superiors to obtain all of the information necessary to secure a patent on the invention. It strikes me as incongruous to rely on the inventor's actual knowledge here if Glaxo indeed thought that knowledge was so insignificant that it did not even merit consultation during preparation of the application.* At the very least, the district court should have given Novopharm the chance at discovery about just what Crookes in fact knew.

But I believe that even absent further discovery the district court could have found a best mode violation in this case. As the district court stated.

> [i]t is undisputed, however, Brereton and other officers within Glaxo believed azeotroping was the best mode of preparing ranitidine hydrochloride for pharmaceutical use, and Glaxo actually utilized this method in the commercial production of ranitidine hydrochloride. These officials within Glaxo made a deliberate choice not to reveal what they believed to be the best mode of making the patented invention, but instead to protect the knowledge as a trade secret.

830 F.Supp. at 881. This recitation suggests that Glaxo set out to isolate Crookes from any knowledge about the azeotroping technique specifically to avoid the best mode disclosure requirements. If true, these circumstances would justify imputing knowledge to Crookes from Brereton and the other Glaxo employees who acted as agents for Crookes during the application process. I would remand to allow the district court to make the necessary factual findings and decide whether to impute that knowledge.

Imputing knowledge to an inventor may be necessary under appropriate circumstances, to protect the public's "paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct." *Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co.*, 324 U.S. 806, 816 [65 USPQ 133] (1945) (endorsing equitable doctrine of unclean hands in patent suits). "The possession and assertion of patent rights are 'issues of great moment to the public.' " *Id.* at 815. And the best mode requirement lies at the heart of this public interest. It is a vital part of the statutory *quid pro quo* that justifies a patent. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200,

* The court finds comfort in the regulations requiring that the inventor sign an oath attesting that he has reviewed the application, 37 C.F.R. §§ 1.41(a), 1.51(a)(2) & 1.63(b)(1)(2), reasoning that Glaxo must have at least let Crookes review the application before it was filed. But none of these regulations speaks to the best mode requirement. Nor are we told how Crookes could sign such an oath if he was never consulted before the application was filed. Perhaps the court has hit upon grounds for a charge of inequitable conduct against Glaxo that everyone else missed.

1210, 18 USPQ2d 1016, 1024 (Fed. Cir. 1991). In return for a seventeen year monopoly the patentee must disclose his invention to the public. But he must go beyond simply informing the public of the bare outlines of the invention. He must also tell what he believes to be the best embodiment of the invention, and he must do so in a way that allows the public to practice that embodiment. This prevents the inventor from obtaining patent protection with a minimal disclosure that reveals only inferior forms of the invention, while retaining for himself the most advantageous modes of carrying the invention into practice. *In re Gay*, 309 F.2d 769, 772, 135 USPQ 311, 315 (CCPA 1962). The court's pinched reading of the best mode requirement surely violates at least the spirit of this rule at the public's expense.

Imputing an agent's knowledge to the principal has sound roots in law and equity. An agent's acts and knowledge can be imputed to the principal when necessary to protect the interests of others, so long as the acts or knowledge in question fall within the scope of the agent's authority. Restatement (Second) of Agency, § 261 (principal liable for agent's fraud within scope of agency), § 274 (knowledge of agent acquiring property for principal imputed to principal); *see also American Soc. of Mechanical Engineers, Inc. v. Hydrolevel Corp.*, 456 U.S. 556, 566 (1982) (principal liable for antitrust violation based on agent's fraud within apparent authority). This precept is firmly rooted in patent law as well, in the traditional doctrine of inequitable conduct, whereby the inventor's duty to disclose material information to the Patent Office is extended to all those involved in the filing and prosecution of a patent application. *See* 37 C.F.R. § 1.56 (1994); *Fox Indus. v. Structural Preservation Sys.*, 922 F.2d 801, 804, 17 USPQ2d 1579, 1581 (Fed. Cir. 1990).

The fact that Crookes' agents knew about the process does not by itself justify imputing that knowledge to him. If he really was unfamiliar with the azeotroping process, that unfamiliarity may simply have resulted from the normal division of labor necessary within a large corporate enterprise. But the district court appears to have inferred a darker subtext — that Glaxo may have deliberately set out to screen this inventor from the azeotroping technique to conceal the process for itself.

The problem is that Glaxo's version of best mode, which the court now adopts, would allow, if not encourage, employers to isolate their employee/inventors from research directed to finding the most advantageous applications for their inventions, knowledge that the inventors would probably have had but for the employer's efforts to keep the work secret. As a result, inventors may have only limited perspective on the real value of their inventions, and can accordingly share only this limited perspective with the public. All the while, the employer/assignee will have a view of the big picture, fully aware, through its other employees, of superior modes of practicing the invention. But the assignee will be under no obligation to disclose those modes to the public. This deliberate subversion of the statutory disclosure would deprive the public of the benefits of the best mode of practicing the invention. There is no reason why this court should condone such abuse of the public trust. *Cf. Precision Instrument Co.*, 324 U.S. at 815.

I would hold that if there truly was such a pattern of deliberate concealment of information that would otherwise have been known to the inventor, the knowledge of those who sought to conceal that information and who now attempt to enforce the patent may be imputed to he inventor. The district court can refuse to enforce the patent and should be given the opportunity to do so with a correct understanding of its powers.

U.S. Court of Appeals
District of Columbia Circuit

Checkers Drive-In Restaurants Inc. v. Commissioner of Patents and Trademarks

No. 94-5027

Decided April 21, 1995

TRADEMARKS AND UNFAIR TRADE PRACTICES

1. Acquisition, assignment, and maintenance of marks — Acquisition through use — Use in commerce (§305.0505)

JUDICIAL PRACTICE AND PROCEDURE

Procedure — Stays — In general (§410.2901)

Trademark registrant involved in cancellation proceeding with debtor in bankruptcy was not precluded by automatic stay provisions of 11 USC 362(a)(1) or 362(a)(3) from filing affidavit setting forth continued use of its registered service mark in commerce as required by 15 USC 1058(a), since purpose of automatic stay is to shelter debtor from demands of creditors and preserve bankrupt's estate pending orderly distribu-